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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,819	08/14/2001	R. Martin Emanuele	19720-0626 (42896-262529)	9900

7590 07/27/2004

John S. Pratt, Esq.  
KILPATRICK STOCKTON LLP  
Suite 2800  
1100 Peachtree Street  
Atlanta, GA 30309-4530

EXAMINER

SCHNIZER, RICHARD A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 07/27/2004

13

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/929,819

Applicant(s)

EMANUELE

Examiner

Richard Schnizer, Ph. D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-13 and 16-28 is/are rejected.
- 7) ☒ Claim(s) 6, 7, 14 and 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 August 2001 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/27/03</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This application was abandoned on 5/1/2003 for failure to timely reply to an office action. A petition to revive the application was granted on 5/12/2004 (Paper No. 12).

An amendment was received and entered as Paper No. 10 on 4/22/04. Claims 17-28 were added as requested. Claims 1-28 are pending and under consideration in this Office Action.

An information disclosure statement was received and entered as Paper No. 12 on 8/27/03.

### ***Compliance with Sequence Rules***

Applicant's submission of 4/22/04 places the application in compliance with the Sequence Rules.

### ***Rejections Withdrawn***

The rejections of claims 1-16 under 35 USC 112, first paragraph for lack of enablement and written description are withdrawn in view of Applicant's amendments.

The rejection of claims 1-16 under 35 USC 112, second paragraph for indefiniteness is withdrawn in view of Applicant's amendments and arguments. The term "genes" is considered to be broad rather than indefinite.

The rejection of claims 1-5, and 9-12 under 35 USC 102 over Kabanov is withdrawn in view of Applicant's amendments.

The rejection of claims 1-4, and 9-12 under 35 USC 102 over Balasubramanian is withdrawn in view of Applicant's amendments.

The rejection of claims 1-3, and 9-11 under 35 USC 102 over Jansen is withdrawn in view of Applicant's amendments.

All rejections under 35 USC 103 are withdrawn in view of Applicant's amendments.

***Priority***

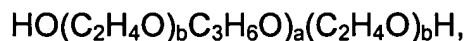
This application is a continuation-in-part of co-pending U.S. application Ser. No. 09/457,771, filed Dec. 9, 1999, which is a continuation of U.S. application Ser. No. 09/104,088, filed Jun. 24, 1998, now abandoned, which is a continuation-in-part of U.S. application Ser. No. 08/926,297, filed Sep. 5, 1997, now abandoned, which is a continuation of U.S. application Ser. No. 08/725,842, filed Sep. 30, 1996, now abandoned, which is a continuation of U.S. application Ser. No. 08/138,271, filed Oct. 15, 1993, now abandoned. Applicant has also claimed priority under 35 USC 120 to 09/368,855, filed Aug. 5, 1999, which is a continuation of U.S. application Ser. No. 08/889,342 filed Jul. 8, 1997, now U.S. Pat. No. 5,990,241, which is a continuation of U.S. application Ser. No. 08/657,161, filed Jun. 3, 1996, now U.S. Pat. No. 5,691,387, which is a division of U.S. application Ser. No. 08/087,136 filed Jul. 2, 1993, now U.S. Pat. No. Re. 36,665, which is a continuation of U.S. application Ser. No. 07/847,874 filed March 13, 1992, now abandoned, which is a continuation-in-part of U.S. application Ser. No. 07/673,289, filed Mar. 19, 1991, now abandoned. The pending claims are not

entitled to this priority claim because they are drawn to compositions comprising a nucleic acid and a copolymer of polyethylene oxide (POE) and polypropylene oxide (POP) polymers, wherein the copolymer is organized such that POP polymers flank a central POE polymer. None of the priority documents provides support for this combination of limitations, so the filing date of the instant claims is the filing date of the instant application, 8/14/01.

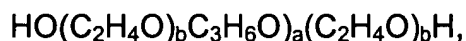
Furthermore, Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. In this case Applicant claims priority in the second paragraph of the specification to "copending U.S. Application Serial No. 09/368,855". This claim does not occur in the first sentence of the specification and it does not include the relationship of 09/368,855 to the instant application. Note also that 09/368,855 has since issued as US Patent 6359014.

***Response to Arguments***

Applicant's arguments filed 4/22/04 have been fully considered but they are not persuasive. Applicant argues that US application 08/138,271 ('271) discloses gene therapy and intracellular delivery of antisense oligonucleotides or other nucleic acid sequences, and also cites Schmolka (J. Am. Oil Chem. Soc 54:110-116, 1977) which discloses the preparation of reverse triblock copolymers (i.e. POP-PEO-POP copolymers). A review of Schmolka shows that this reference teaches how to make poloxamers, meroxapols, poloxamines (i.e. octablock copolymers), and pluradot polyols. See Figs. 1-4. However, Applicant has failed to provide any evidence or logic to indicate that the '271 application relied upon Schmolka for its disclosure of reverse triblock copolymers. A review of the specification of '271 reveals that the invention claimed therein was directed to admixtures of a therapeutic compound (e.g. a nucleic acid) and an effective amount of a block copolymer of the general formula:



which is the general formula of a poloxamer. The specification of '271 does not appear to disclose or describe any copolymer other than a poloxamer, except by reference to Schmolka. The Schmolka reference is referred to at page 17, lines 12-18, as providing a description of how to prepare the copolymers represented in Fig. 1 of '271. Fig. 1 discloses 21 copolymers, 17 of which are products of BASF corporation having trade names beginning with a prefix 'L', 'P', or 'F' and not containing the letter 'R'. BASF corporation uses the letter 'R' to denote reverse triblock copolymers, so none of these 17 copolymers appears to be reverse triblock copolymers. The remaining 4 copolymers are CRL 336, CRL 1190, CRL 1235, and CRL 8950. There is nothing in the specification to suggest that any of these compounds is a reverse triblock copolymer, and Applicant has provided no evidence or argument indicating such. In view of the available evidence, one of skill in the art would consider the specification of '271 to be directed to poloxamers of the general formula:



and would consider the reference to Schmolka as guidance for to how to make these poloxamers. In the absence of any disclosure of in the specification of '271 of reverse triblock copolymers, one of skill in the art would not refer to Schmolka for guidance as to how to make these compounds.

For these reasons, the filing date of the instant claims must be the filing date of the instant application, 8/14/01.

### ***Claim Objections***

Claim 3 is objected to because it contains a comma immediately followed by a period.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 17-28 recite a variety of ranges including hydrophobe molecular weights between approximately 3250 and 20000 Da, between about 5000 and 20000 Da, between about 7000 and 20000 Da, and also hydrophile percentages between 1 and 10% and between 80 and 90%. The specification provides no written support for this range, and there is no evidence that Applicant contemplated these specific ranges at the time the invention was filed, so they represent new matter.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 8-13, and 16-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Lemieux et al (US Patent 6,359,054, issued 3/19/02).

Lemieux teaches methods of delivering to a patient a composition comprising POP-POE-POP block copolymers and nucleic acids (see e.g. claim 13 at column 49). Nucleic acids include expression vectors, antisense, ribozymes, or oligonucleotides (see column 21, lines 15-29). Absent evidence to the contrary, antisense molecules will also function as triplex-forming compounds. The POP-POE-POP block copolymers useful in the invention include at least the following compounds that meet instant claim limitations (with approximate hydrophobe weight and approximate hydrophile % in parentheses) 22R4 (2200, 60), 25R1 (2500, 10), 25R2, (2500, 20), 25R4 (2500, 40), 25R5 (2500, 50), 31R1 (3100, 10), 31R2 (3100, 20), and 31R4 (3100, 40), 110R1 (4800, 10), 110R2 (4800, 20), 110R3 (4800, 30), 150R1 (6700, 10), 150R4 (6700, 40), 150R8 (6700, 80) (see column 14, line 34-36 to column 15, line 31. For example, 25R1 meets the limitations of claims 1-5, 8-13, 16, 21, and 27; 150R8 meets the limitations of claims 1-5, 8-13, 16-20, 22, 23-26, and 28; and 25R2 150R1 meets the limitations of claims 1-5, 8-13, 16-21, and 23-27. It is noted that claim 19 recites a hydrophobe molecular weight range of "between approximately 7000 and 2000 Daltons", whereas 150R8 and 150R1 have an approximate hydrophobe molecular weight of 6700. 150R1 and 150R8 are considered to meet the limitation "between approximately 7000 and 2000 Daltons" because the specification does not define "approximately" in this context,

so "approximately 7000" is reasonably construed as meaning 7000 +/- 10% (700 Da). Similarly, limitations requiring hydrophile percentage of greater than about 1% and less than about 10%, or greater than about 80% and less than about 90%, are considered to be met by compositions having about 10% or about 80% hydrophile.

Thus Lemieux anticipates the claims.

### ***Response to Arguments***

Applicants arguments filed 4/22/04 have been fully considered but are unpersuasive. Applicant argues that Lemieux cannot be considered prior art because the effective filing date of the instant application is 10/15/93. This is unpersuasive for the reasons set forth above under Priority, i.e. the effective filing date of the instant application is 8/14/01. Applicant's argument that Lemieux fails to teach reverse block copolymers with a POP portion of greater than 3100 Da as required by claims 17-19 and 23-25, or reverse block copolymers comprising a hydrophile percentage of less than 10% or greater than 80% as claimed in newly added claims 21, 22, 27, and 28. As discussed above, Lemieux teaches a variety of reverse block copolymers with a POP portion of greater than 3100 Da, i.e. 110R1 (4800, 10), 110R2 (4800, 20), 110R3 (4800, 30), 150R1 (6700, 10), 150R4 (6700, 40), 150R8 (6700, 80). Also, all of the range limitations in the claims are set forth such that the upper and lower limits are approximates. As discussed above, the specification does not define "approximately", and it is deemed reasonable to interpret this as +/- 10%. In this interpretation, reverse block copolymers of Lemieux that have about 10% or 80% hydrophile, such as 150R8

and 150R1, meet the limitations of claims 21 and 27, and 22 and 28, respectively. For these reasons the rejection is maintained.

### ***Conclusion***

Claims 6, 7, 14, and 15 are objected to as depending from a rejected claim, but would be allowable if rewritten in independent form with all the limitations of the parent claim(s).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the

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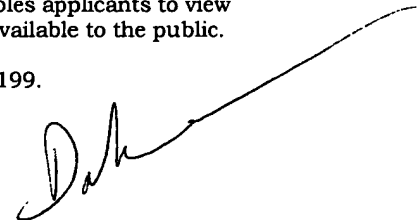
hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, John Leguyader, be reached at 571-272-0760. The official central fax number is 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Richard Schnizer, Ph.D.



DAVE T. NGUYEN  
PRIMARY EXAMINER